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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,356	03/02/2004	Eric Fugelsang	11830/6	8968

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KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,356	FUGELSANG ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☒ Claim(s) *19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 6 is objected to because of the following informalities: in claim 6, there is an inconsistency between the language of the preamble and certain portion or portions of the body of the claim (i.e. preamble recites a spacer inferentially whereas lines 6 and 8 positively recite "...the spacer..."), thereby making the scope of the claim unclear. Applicant is required to clarify what the claim is intended to be drawn to, i.e. either a mouthpiece alone or the combination of a mouthpiece and a spacer and applicant is required to make the language of the claim consistent with his intent. Appropriate correction is required.

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1-5 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5 of prior U.S. Patent No. 6,698,422. This is a double patenting rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 6,7,15 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith ('140).

As to claim 6, Smith (fig.1) discloses a mouthpiece (22) for a spacer (17) with an exhalation valve mechanism (10) for use by a patient to inhale medication in more than one breath, comprising: a flexible, elastic material (11); a first end (#23 of fig.1 adjacent screw threads); and a distal end (#22 of fig.1), wherein the distal end is shaped to fit the mouth of the patient, and wherein the first end is shaped to elastically and fixedly engage the spacer, and wherein air exhaled by the patient exits (via exit passage 27) the mouthpiece by passing between the flexible, elastic material (11,31) of the mouthpiece and the spacer (17).

As to claim 7, the first end of the mouthpiece of Smith includes at least one exhalation tab (31).

As to claim 15, Smith (col.2, lines 46-50) discloses an inhaler for delivery of medication from at least one MDI canister via aperture (18).

6. Claims 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Barnes, Jr. et al. ('900).

As to claim 16, Barnes, Jr. et al. disclose an inhaler for delivery of medication from at least one canister (100) to the lungs of a patient by inhalation through the patient's mouth, the at least one canister has a compression spray outlet (104), the inhaler comprising: a cowling (fig.1) having a support structure, wherein the support structure has a first end, an opposite end, an inner surface, and an outer surface, wherein the opposite end of the support structure is open, allowing the patient to insert at least one container into the cowling, and wherein the shape of the inner surface of the cowling is selected to guide each canister into the first end, and to hold each canister in place within the cowling; a housing (12), wherein the housing further comprises a chamber receiving section, a cowling receiving section, a support, a fresh air inlet (29), at least one compression spray outlet compression mechanism (14,46,38), an enclosed passage (16), and wherein the cowling is fixedly seated in the cowling receiving section, and wherein the cowling receiving section has at least one cowling receiving inlet port (20), and wherein, the compression spray outlet (104) of the at least one canister extends through the corresponding cowling receiving section inlet port, and into the enclosed passage (16) of the housing (12) and ends in the chamber receiving section, wherein the chamber receiving section is an opening (22) in the housing; an actuator lever (14) having a lever arm and a distal end, wherein the distal end is pivotally mounted (34,60) on the support of the housing, whereby the distal end engages (38) at least one canister, when the actuator lever is depressed by the patient; a mouthpiece (54) comprising a first end, wherein the first end is shaped to fit in the patient's mouth and a distal end, opposed to the first end, and wherein the distal end is comprised of a

flexible, elastic material (66); a chamber (16) further comprising a mouthpiece mating section (figs.13 and 14), a chamber body and a housing mating section, wherein the housing mating section comprises a first opening (22) in the chamber body, wherein the chamber body comprises a shell, and wherein the mouthpiece mating section comprises a second opening (26) in the chamber body, and wherein the distal end of the housing mating section of the chamber engages the chamber receiving section of the housing, and wherein the chamber body opposes the actuator lever, whereby the patient can depress the actuator lever by squeezing the lever arm to the chamber body, and whereby the compression spray outlet of at least one canister is activated, whereby medication enters into the enclosed passage (16) of the housing and the chamber body, and whereby, when the patient inhales through the mouthpiece, fresh air enters the enclosed passage through the fresh air inlet of the housing, whereby the mixture of air and medication in the enclosed passage of the housing and the chamber body is drawn into the lungs of the patient.

As to claim 17, Barnes, Jr. et al. disclose a valve assembly (24), and wherein the valve assembly is fixed on the chamber body, and wherein the valve assembly opens during inhalation and closes against the valve body during exhalation (col.5, lines 7-45), whereby medication and air are prevented from exiting through the valve assembly.

As to claim 18, the valve assembly (24) of Barnes, Jr. et al. comprises a diaphragm valve (28) and valve body (31,32), wherein the diaphragm valve opens during inhalation and closes against the valve body (31,32) during exhalation, preventing exhaled air from entering the chamber body.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith ('140).

As to claims 8 and 9, Smith discloses the flexible elastic material (11) to be formed from flexible material (col.3, line 17) but does not expressly disclose the particular flexible material. It would have been obvious to make the flexible material of Smith from any material which is flexible including silicone rubber, neoprene rubber, butyl rubber and latex as an obvious matter of design choice because these materials are typically employed by the skilled artisan to make inhalation and exhalation valves in the respiratory arts. Further, the use of any of these materials as the flexible material of Smith would have provided known or expected results of seating and unseating in response to patient inhalation and exhalation.

As to claims 10 and 11, the particular dimensions and cracking (exhaust) pressure of the flexible elastic material (11) of Smith can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular thickness or cracking pressure. The dimensions (thickness) and cracking pressure of the flexible elastic material of Smith would have to have been varied in dependence upon the individual patient's sex, age, respiratory capacity and in dependence upon the particular

respiratory disease being treated. For example, adult patients would have a greater respiratory capacity than children and therefore, require a thicker valve having a larger cracking pressure.

9. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith ('140) in view of Barnes, Jr. et al. ('900).

The difference between Smith and claim 12 is the flexible, elastic material of the patient end is thicker than the flexible, elastic material of the chamber body end.

Barnes, Jr. et al. (figs.13 and 14), in a mouthpiece for a spacer, teach a thicker patient end for the purpose of providing an annular lip for a patient to grip the mouthpiece with the patient's teeth for securely holding the mouthpiece within the patient's mouth.

It would have been obvious to increase the thickness of the patient end of the mouthpiece of Smith because it would have provided an annular lip for a patient to grip the mouthpiece with the patient's teeth for securely holding the mouthpiece within the patient's mouth as taught by Barnes, Jr. et al..

As to claim 13, the thickness of the mouthpiece of Barnes, Jr. et al. as illustrated in figs.13 and 14 occurs abruptly.

As to claim 14, the distance over which the change of thickness occurs in Barnes, Jr. et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular distance including 1cm. Providing a more gradual change in the thickness of the mouthpiece of Barnes, Jr. et al. would have provided a smoother transition and a more comfortable mouthpiece.

Allowable Subject Matter

10. Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
June 03, 2005